

## PATENT COOPERATION TREATY

PCT

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 4826WO382BIO	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. PCT/EP2005/001390	International filing date ( <i>day/month/year</i> ) 11 February 2005 (11.02.2005)	Priority date ( <i>day/month/year</i> ) 27 February 2004 (27.02.2004)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant BIOIBERICA, S.A.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 7 sheets, including this cover sheet.  
  
In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:
 

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application
4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 338 82 70	Date of issuance of this report 30 August 2006 (30.08.2006)
	Authorized officer  Yolaine Cussac  e-mail: pt11@wipo.int

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  see form PCT/ISA/220	REC'D 17 OCT 2005		PCT WIPO PCT WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43 <i>bis</i> .1)
	Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet)		
	Applicant's or agent's file reference see form PCT/ISA/220		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/EP2005/001390	International filing date (day/month/year) 11.02.2005	Priority date (day/month/year) 27.02.2004	
International Patent Classification (IPC) or both national classification and IPC A61P19/02, A61K31/737			
Applicant BIOIBERICA, S.A.			

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application



2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Authorized Officer
 <p>European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465</p>	<p>Blott, C</p> <p>Telephone No. +49 89 2399-7538</p> 

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/EP2005/001390

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/EP2005/001390

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 18

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 18 are so unclear that no meaningful opinion could be formed (*specify*):

**see separate sheet**

- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 18
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
  - the written form ☐ has not been furnished
  - ☐ does not comply with the standard
  - the computer readable form ☐ has not been furnished
  - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/EP2005/001390

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**Box No. V Reasoned statement under Rule 43bis.1(a)(I) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	
	No: Claims	1-25
Inventive step (IS)	Yes: Claims	
	No: Claims	1-25
Industrial applicability (IA)	Yes: Claims	1-25
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The application does not meet the requirements of Article 6 PCT, because claim 18 is not clear.

The term "carrageenan polysulfate" used in independent claim 18 is not clear since carrageenans are natural polysulfated polysaccharides.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

2. References:

- D1: DATABASE CA [Online] CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; MINAMI, S. ET AL: "Veterinary-clinical uses of curdlan sulfate" retrieved from STN Database accession no. 1999:492587
- D2: WO 03/006645 A (IMCLONE SYSTEMS INCORPORATED; BOHLEN, PETER; HICKLIN, DANIEL; KUSSIE,) 23 January 2003 (2003-01-23)
- D3: US-A-4 021 545 (NAIR ET AL) 3 May 1977 (1977-05-03)
- D4: US 2003/181416 A1 (COMPER WAYNE D) 25 September 2003 (2003-09-25)
- D5: MIYAMOTO KEIICHI ET AL: "Novel plasma-separation dilayer gellan-gellan-sulfate adsorber for direct removal of extra domain A containing fibronectin from the blood of rheumatoid arthritis patients" INTERNATIONAL JOURNAL OF BIOLOGICAL MACROMOLECULES, vol. 30, no. 3-4, 18 June 2002 (2002-06-18), pages 197-204, XP009054555 ISSN: 0141-8130
- D6: EP-A-0 561 379 (ASAHI MEDICAL CO., LTD) 22 September 1993 (1993-09-22)
- D7: US-A-4 699 900 (BAYOL ET AL) 13 October 1987 (1987-10-13)
- D8: WO 92/13541 A (HOECHST AKTIENGESSELLSCHAFT) 20 August 1992 (1992-08-20)
- D9: WO 02/36132 A (LABORATOIRES GOEMAR S.A; YVIN, JEAN-CLAUDE; ALBAN, SUSANNE; FRANZ, GER) 10 May 2002 (2002-05-10)

D1: Curdlan sulfate - treatment of arthritis in animals

D2: Laminarin sulphate - inhibitor of human heparanase activity - treatment of arthritis

D3: Inulin poly-H-sulfate - treatment of rheumatoid arthritis

D4: Sulphated polysaccharides such as curdlan sulfate - antibiotic activity, treatment of arthritic diseases also encompassed

D5: Plasma-separation dilayer gellan-gellan-sulfate adsorber for direct removal of extra domain A containing fibronectin from the blood of rheumatoid arthritis patients

D6: Leucocyte removing apparatus used in extracorporeal circulation for removing leukocytes from blood of a patient of autoimmune diseases such as rheumatoid arthritis containing an adsorptive filter medium comprising negative ligands such as polysaccharide sulfates, eg. pectin sulfate, inulin sulfate, alginic acid sulfate, carrageenan sulfate etc.

D7: Xylan sulfates - arthrosis

D8: Use of substd. polysaccharides such as sulfated xylan, dextran, xanthan, araban - treatment of arthrosis

D9: Treatment of inflammatory diseases associated with non-specific inflammatory reactions using laminarin sulfate

3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

The documents D1-5 already disclose the use of sulphated polysaccharides such as those enumerated in claim 1, e.g. curdlan sulfate, in the treatment of arthritic diseases.

The same reasoning applies, *mutatis mutandis*, to the subject-matter of the corresponding independent claims 19 and 23 which therefore are also considered not new.

Dependent claims 2-17, 20-22, 24-25 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see documents D1-9 and the corresponding passages cited in the search report.